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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,684	01/29/2001	Eiichi Kitazono	Q62906	3250

7590 11/17/2003

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Washington, DC 20037-3213

EXAMINER

HARLAN, ROBERT D

ART UNIT	PAPER NUMBER
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1713

DATE MAILED: 11/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

CLO 11

Office Action Summary

Application No.

09/744,684

Applicant(s)

KITAZONO ET AL.

Examiner

Robert D. Harlan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. The IDS filed by Applicants on 07/18/03 and Amendment with Petition for Time Extension filed by Applicants on 08/11/03 have been entered.

Response to Amendment/Arguments

2. Applicant's amendment and arguments filed on 03/12/02 have been fully considered and they are found persuasive.

3. The rejection of claims 1-5 and 8-15 under 35 U.S.C. 103(a) as being unpatentable over the combination of JP Publication No. 09-143062 (hereinafter "'062"), JP Publication No. 04-266742 (hereinafter "'742"), International Publication No. WO 92/10154 (hereinafter "'154") and JP Publication No. 01-233212 (hereinafter "'212") is withdrawn.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at

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the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-5 and 8-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of JP Publication No. 09-143062 (hereinafter "'062") and Ebert et al., WO 92/10154. '062 discloses a pressure sensitive adhesive composition that contains in prescribed amounts (a) an acrylic pressure-sensitive adhesive containing a copolymer, (b) a polyhydric alcohol, and (c) a prescribed fatty acid metal salt, and a tape containing the pressure sensitive adhesive useful in adhesive drug composition. '062 differs from the present invention in that '062 does not teach the combination of the polyhydric alcohol with a sorbitan ester compound and metal salt. Ebert teaches in

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analogous art penetration enhancers consisting of a sorbitan ester in combination with a C₁₋₄ aliphatic alcohol. See Ebert, pages 14-16. In view of Ebert, one having an ordinary skill in the art would be motivated to modify '062 by using an penetration enhancer. Such modification would be obvious because one would expect that the use of adhesive compositions for percutaneous applications as taught by '062 would be similarly useful and applicable to the penetration enhancer taught in Ebert.

Conclusion

7. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 07/18/03 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

8. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

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statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert D. Harlan whose telephone number is (703) 306-5926. The examiner can normally be reached on Mon-Fri, 10 AM - 8 PM.

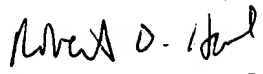
10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David W. Wu can be reached on (703) 308-2450. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9559 for regular communications and (703) 872-9559 for After Final communications.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1495.

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Robert D. Harlan
Primary Examiner
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rdh

November 13, 2003